



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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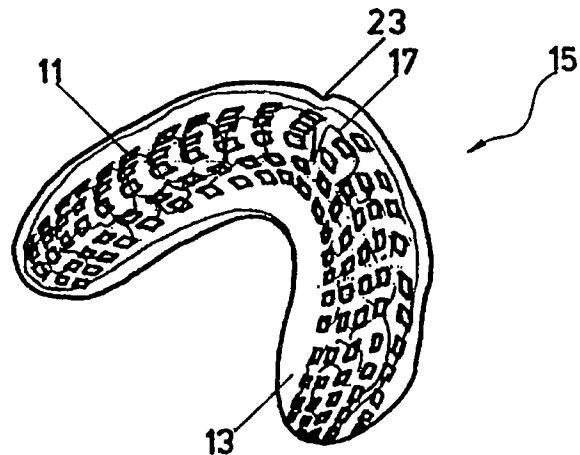
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With international search report.

(54) Title: IMPROVED MATERIAL FOR MOUTHGUARDS

## (57) Abstract

A mouthguard (15) made from orally acceptable plastics material. The mouthguard has a plurality of enclosed cavities (11) at spaced locations arranged in at least a substantial part of the mouthguard.



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TITLE

"IMPROVED MATERIAL FOR MOUTHGUARDS"

FIELD OF THE INVENTION

THIS INVENTION relates to an improved material  
5 for mouthguards and to a mouthguard made from that material.

BACKGROUND OF THE INVENTION

The invention will be described by way of example with reference to mouthguards intended to be used  
10 while taking part in body contact sports. It should be appreciated that this is by way of example only and that the mouthguard of the invention may be used for therapeutic purposes also. For example the mouthguard may be used for treating temporomandibular disorders or  
15 the like.

DISCLOSURE OF THE INVENTION

Mouthguards are typically made from plastics material such as an ethylene vinyl acetate copolymer (EVA) and fall into three specific categories. The  
20 mouthguards are either stock products premoulded and made in a variety of sizes, home or self mouldable to suit the physical characteristics of the user or custom moulded to suit the characteristics of the user. The stock mouthguards are typically the cheapest and least  
25 effective in use while the custom moulded and shaped mouthguards are the most expensive and effective in their impact absorbent properties.

Little has been done to improve upon the characteristics and properties of mouthguards to enhance  
30 their effectiveness in protecting the teeth, jawbone and intraoral tissues from injury while the wearer takes part in body contact sporting activities such as boxing, football and the like.

German patent specification 4011204 discloses a  
35 mouthguard material consisting of an EVA copolymer material, polycaprolactone and colorants and perfumes and PVA to reduce the softening point of the resultant mouthguard for ease of manipulation and shaping.

United States patent specification 4920984 relates to a mouthguard material which may be custom shaped or moulded employing a teeth impression cast pressed against softened thermoplastic sheet material  
5 which increases in thickness from one end to the other.

Australian patent specification 633269 discloses a mouthguard made from an EVA copolymer having a softening point higher than the normal temperature of an oral cavity but lower than the highest temperature  
10 that the oral cavity can endure so that the user may adapt the mouthguard to fit the mouth by biting onto it after it has been heated. The shaping procedure may be repeated if the shape or configuration of the teeth should change.

15 Earlier proposals as well as providing materials enabling custom or self shaping of the mouthguard have also suggested the use of other additives to the material of construction to enhance the characteristics of the material. For example, United  
20 States patent specification 4044762 suggested the inclusion of not greater than 5% sodium fluoride, stannous fluoride or sodium fluorosilicate in the material of construction to simultaneously provide prophylactic treatment of the teeth.

25 There has been little activity in the construction of mouthguards in an attempt at enhancing the impact absorption properties other than the change in thickness referred to in United States Patent 4920984.

It is an object of the invention to provide an  
30 improved mouthguard material and a mouthguard made from that material which provides enhanced impact absorbent properties.

According to one aspect, the invention provides a mouthguard material made of orally acceptable plastics  
35 material, the mouthguard material having a plurality of enclosed cavities therein at spaced locations arranged in at least a substantial part of the material.

The enclosed cavities may be of any suitable

size and shape. For example, the cavities may have irregular shapes or regular shapes such as spherical or cylindrical shapes. The cavities need not be regularly spaced. For example, the cavities may occur randomly spaced throughout the material. The cavities in the material need not all be the same size or shape. However, it is preferred that the cavities employed in the material all be similar in size and shape.

The enclosed cavities may be present as voids in the material. If desired, the cavities may be filled with gas or liquid to enhance the impact absorption characteristics of the material. In one embodiment, the cavities may be filled with a synthetic material different from the substance from which the mouthguard material is predominantly made.

It is preferred that the mouthguard material be made from an ethylene vinyl acetate copolymer (EVA) substitute or equivalent. Additives may be added to the EVA to provide special properties for the mouthguard material. Preferably a copolymer of ethylene and about 20% by weight vinyl acetate is employed. Colorants, perfumes and softening agents may also be added.

According to another aspect, the invention provides a mouthguard made of orally acceptable plastics material and having a plurality of enclosed cavities therein at spaced locations arranged over at least a substantial part of the mouthguard.

One way in which the cavities may be formed is by employing an inner layer of sheet material in which a plurality of spaced apertures are formed and an upper and a lower layer of sheet material bonded to opposed sides of the inner layer to thereby close off the apertures to form the enclosed cavities. Other ways of forming the cavities may also be employed.

#### 35 DISCLOSURE OF THE DRAWINGS

Preferred aspects of the invention are described with reference to the drawings in which:

Figure 1 is a spectral analysis of a preferred

material from which the mouthguard of the invention may be made;

Figure 2 is a graph showing comparative test results for materials from which mouthguards according to the invention may be made and standard mouthguard material;

Figure 3 is a plan view of a blank of material from which a mouthguard in accordance with the invention may be made;

Figure 4 shows a perspective view of a mouthguard made from the blank of Figure 3;

Figure 5 is an exploded perspective view of a cast and the mouthguard shown in Figure 4; and

Figure 6 is a graph of a thermal gravimetric analysis of the material identified by Figure 1.

#### DETAILED DESCRIPTION OF THE DRAWINGS

Figure 1 is a Perkin-Elmer spectral trace which identifies the preferred material from which mouthguards according to the invention may be made. The material is sold under the trade mark STAY-GUARD and is made by World Wide Dental Inc in Clearwater, Florida, United States of America. Figure 6 shows a graph of a thermal gravimetric analysis of this material. The material is an ethylene vinyl acetate copolymer with 20% by weight vinyl acetate.

The mouthguard may be pre-moulded and thus be of the more basic type of mouthguard previously mentioned. Alternatively the mouthguard may be user mouldable to suit the physical characteristics of the user. In yet another alternative, the mouthguard material of the invention may be custom moulded using a cast or impression taken of the user's physical characteristics.

Figure 2 is a graph showing impact results for the preferred EVA material identified by the spectral analysis shown in Figure 1 but not having voids or cavities in accordance with the invention. The sample identified as standard is such an EVA material.

Sample 1 is made from the same EVA material but

has enclosed cavities formed in it. The cavities have a size of 2 x 2 mm and are separated by 2 mm wide borders. Sample 2 once again is made of the preferred EVA material and the cavities are 2 x 2 mm in size and separated by 1.00 mm borders. Sample 3 is made from the preferred EVA material and has cavities 3 x 3 mm in size separated by 1 mm borders.

The samples tested had a nominal thickness of about 4 mm and were all of the same dimensions. A minimal wall thickness may be provided on opposite side faces of the material overlying the cavities. A known force was applied to each of the sample materials and the force transmitted through the samples is shown in the graph. Sample 3 provided the greatest impact absorbing properties.

Figure 3 shows a blank of material from which a mouthguard in accordance with the invention may be made. The blank 10 is in the general shape necessary for a mouthguard and may either be premoulded into standard sizes or softened and moulded to conform to the shape required by a user.

Not all of the blank 10 is provided with enclosed cavities shown generally by the numeral 11. These cavities 11 are confined within a border 12 such that when moulded the area defined by the border 12 extends over the ends of the teeth of the user and substantially over both sides of the teeth. A peripheral zone 13 is free of cavities.

Figure 4 is a perspective view of a mouthguard 15 made from the blank like that of Figure 3. The view shown is above looking into the valley within which teeth are received by the mouthguard. The cast 16 shown in Figure 5 has been used as a mould for forming the mouthguard 15 and depressions 17 into which teeth project are clearly visible. Portions of the zone 13 may be trimmed away as required or deemed necessary.

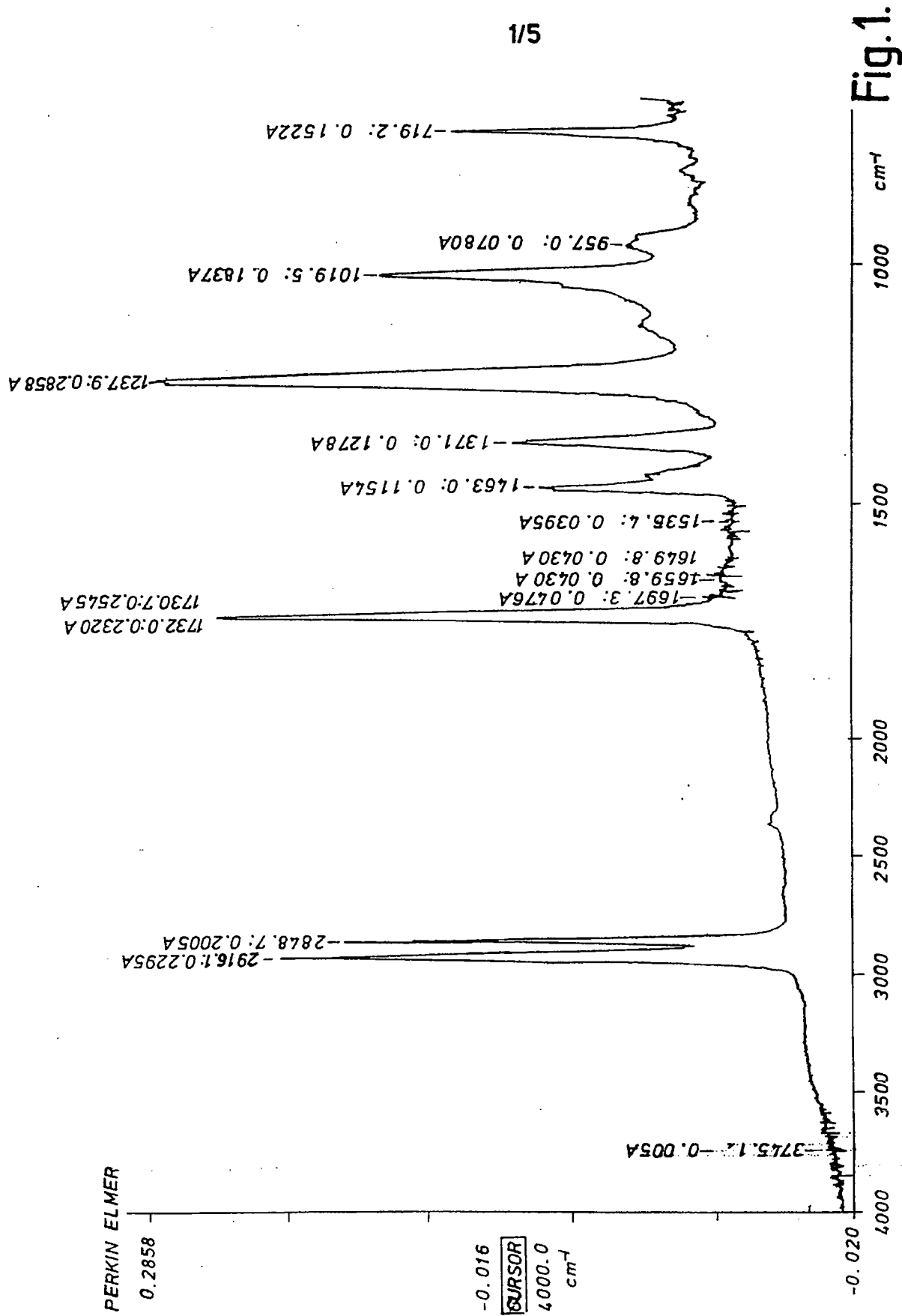
Figure 5 shows a view of a cast on which a mouthguard may be formed. The cast 16 is representative

of an upper set of teeth 18. A blank of material in accordance with the invention is moulded into a mouthguard 19. Enclosed cavities 20 extend over a portion of the guard 19 and at least cover or extend over the teeth when in use. A palate portion 21 shown in this figure is trimmed in the finished mouthguard 15 shown in Figure 4. Likewise the free edge 22 may be trimmed to suit to provide a recess 23 (see Figure 4) to accommodate the frenum on the inner surface of the upper lip of the wearer of the guard.

CLAIMS:-

1. A mouthguard material made of orally acceptable plastics material, the mouthguard material having a plurality of enclosed cavities therein at spaced locations arranged in at least a substantial part of the mouthguard material.
2. The mouthguard material of Claim 1 wherein the enclosed cavities are regularly spaced.
3. The mouthguard material of Claim 1 wherein the cavities have a regular shape.
4. The mouthguard material of Claim 1 wherein the cavities are all of a similar size and shape.
5. The mouthguard material of Claim 1 including a peripheral zone free of said enclosed cavities.
6. The mouthguard material, of any one of Claims 1 to 5 made from an ethylene vinyl acetate copolymer.
7. The mouthguard material of Claim 6 wherein the ethylene vinyl acetate copolymer includes at least 20% by weight vinyl acetate.
8. The mouthguard material of Claim 1 wherein the cavities are filled either with a liquid or a gas.
9. The mouthguard material of Claim 1 wherein the cavities are filled with a synthetic material different from the orally acceptable plastics material.
10. A mouthguard made of an orally acceptable plastics material and having a plurality of enclosed cavities therein at spaced locations arranged in at least a substantial part of the mouthguard.
11. The mouthguard of Claim 10 wherein the enclosed cavities are regularly spaced.
12. The mouthguard of Claim 10 wherein the enclosed cavities have a regular shape.
13. The mouthguard of Claim 10 wherein the enclosed cavities are all of a similar size and shape.
14. The mouthguard of Claim 10 including a peripheral zone free of said enclosed cavities.
15. The mouthguard of any one of Claims 10 to 14 made from an ethylene vinyl acetate copolymer.

16. The mouthguard of Claim 15 wherein the ethylene vinyl acetate copolymer includes at least 20% by weight vinyl acetate.
17. The mouthguard of Claim 10 wherein the cavities  
5 are filled either with a liquid or a gas.
18. The mouthguard of Claim 10 wherein the cavities are filled with a synthetic material different from the material from the orally acceptable.



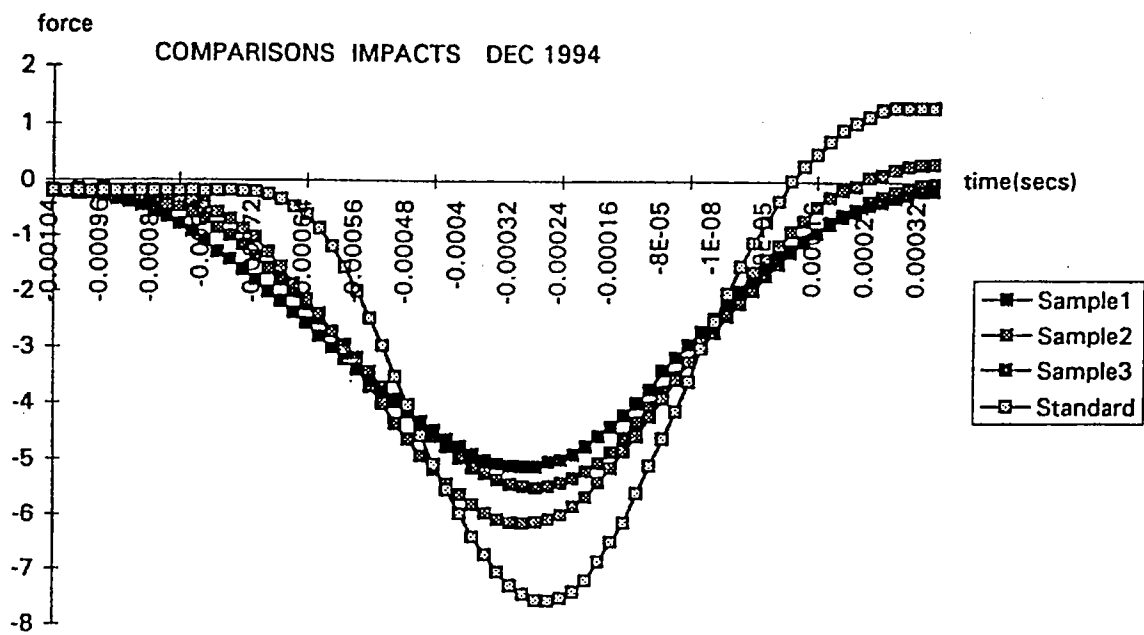


Fig.2.

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Fig. 3.

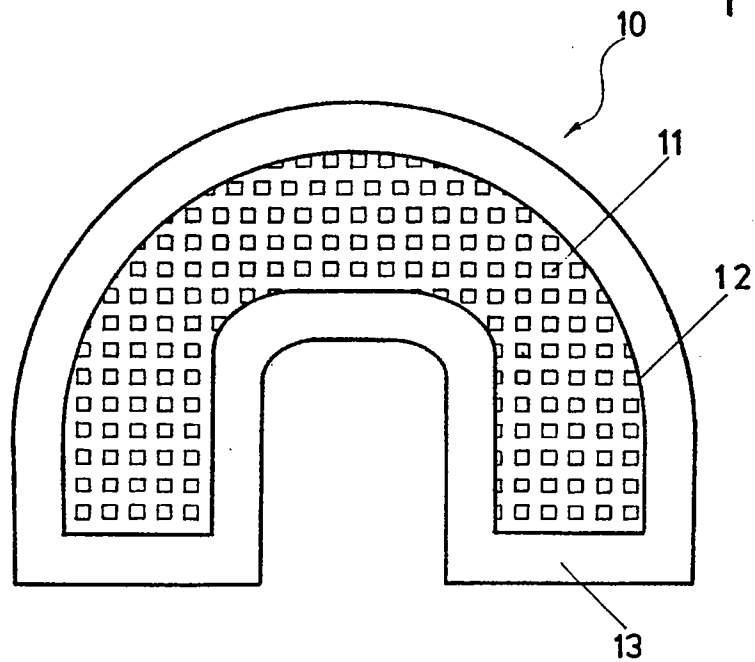


Fig. 4.

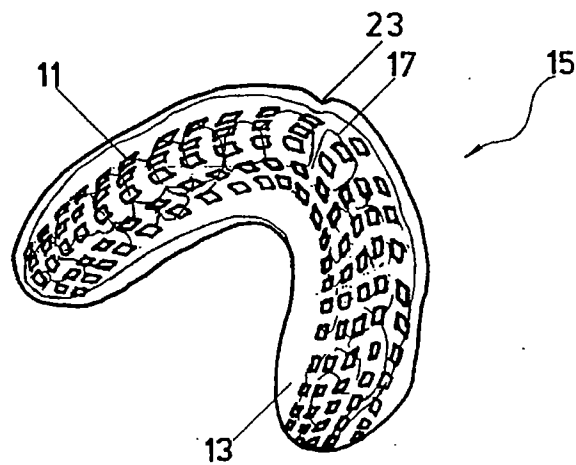
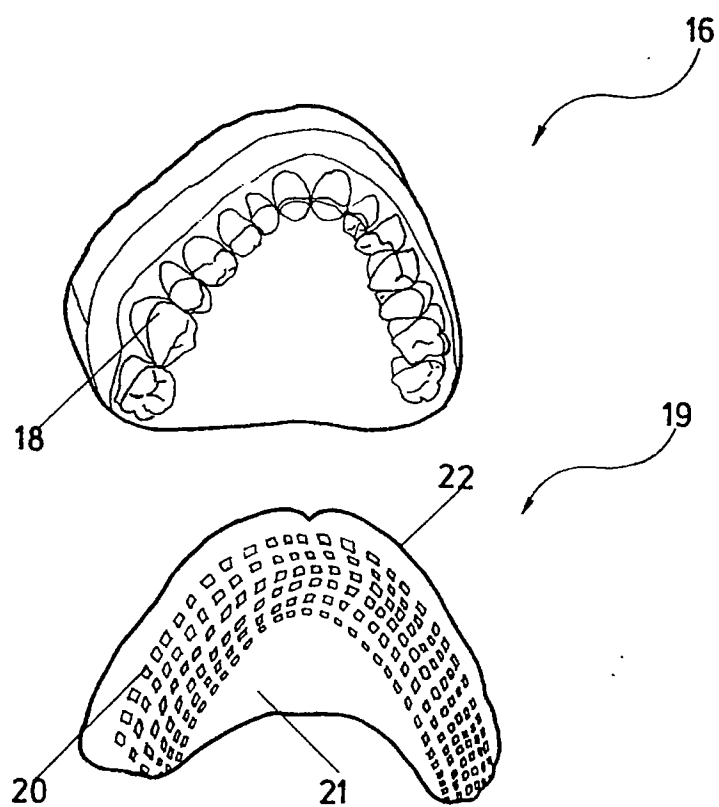


Fig.5.



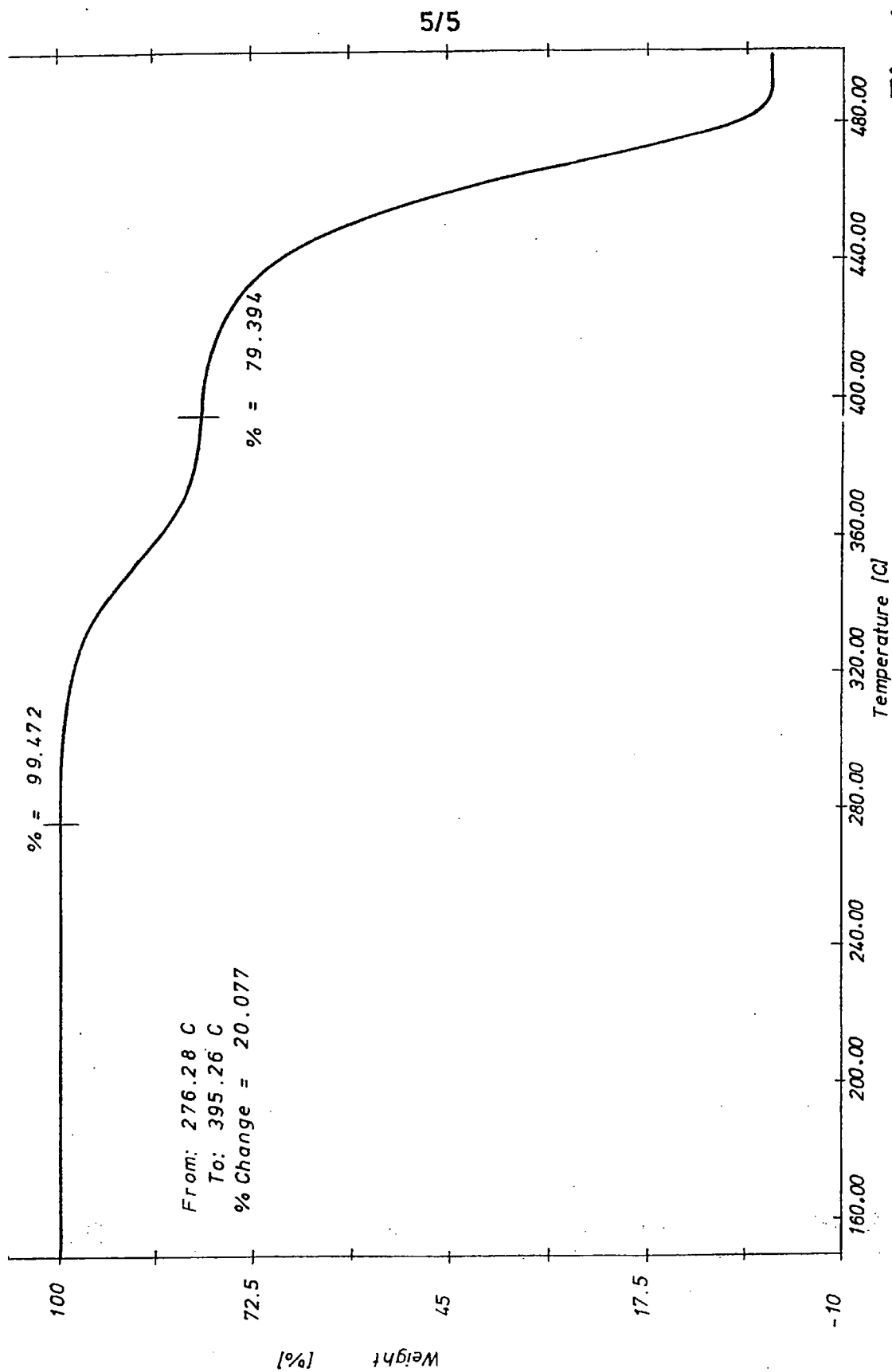
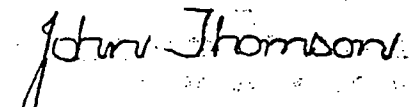


Fig. 6.

## INTERNATIONAL SEARCH REPORT

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> Int. Cl. <sup>6</sup> A63B 71/08, A61C 5/14  According to International Patent Classification (IPC) or to both national classification and IPC				
<b>B. FIELDS SEARCHED</b>  Minimum documentation searched (classification system followed by classification symbols) IPC A63B 71/08, A61C 5/14  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: as above  Electronic data base consulted during the international search (name of data base, and where practicable, search terms used)				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.		
A	JP,A, 05-300915 (MOLTEN CORP) 16 November 1993 See ABSTRACT	All		
A	EP,A, 490137 (GORE & ASSOC GMBH) 17 June 1992 See entire document.	1 to 9		
A	JP,A, 04-028381 (MITSUBISHI PETROCH KK) 30 January 1992 See Abstract	All		
A	JP,A, 03-244480 (MORUTEN KK) 31 October 1991 See Abstract	All		
<div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.         </div> <div> <input checked="" type="checkbox"/> See patent family annex.         </div> </div>				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;">           * Special categories of cited documents :            "A" document defining the general state of the art which is not considered to be of particular relevance            "E" earlier document but published on or after the international filing date            "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)            "O" document referring to an oral disclosure, use, exhibition or other means            "P" document published prior to the international filing date but later than the priority date claimed         </td> <td style="width: 50%; vertical-align: top;">           "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention            "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone            "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art            "&amp;" document member of the same patent family         </td> </tr> </table>			* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
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Date of the actual completion of the international search 19 May 1995		Date of mailing of the international search report 13 JUNE 1995 (13.06.95)		
Name and mailing address of the ISA/AU  AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA  Facsimile No. 06 2853929		Authorized officer    <b>J W THOMSON</b>  Telephone No. (06) 2832214		

# INTERNATIONAL SEARCH REPORT

international application no.

PCT/AU 95/00083

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate of the relevant passages	Relevant to Claim No.
A	CA,A, 2024799 (ADELL LS) 25 January 1991 See Abstract.	All
A	FR,A, 2576798 (SAMETZKY S) 8 August 1986 See entire document.	All
A	SE,A, 8404661 (WALLNER P) 17 March 1985 See Abstract.	All
A	US,A, 3319626 (DAVID K. LINDSAY) 16 May 1967 See entire document.	All
A	US,A, 3247844 (Hyman H. BERGHASH) 26 April 1966 See entire document.	All
A	US,A, 3207153 (Sol GOLDSTEIN) 21 September 1965 See entire document.	All

**INTERNATIONAL SEARCH REPORT**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
EP	490137	CA	2057194	DE	9016713	FI	915788
		US	5361410				
CA	2024799	US	5082007				
END OF ANNEX							